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No. 03-114

Supreme Court, U.S.
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In The
Supreme Court of the United States

SOUTH CAROLINA MEDICAL ASSOCIATION, *et al.*,

Petitioners,

v.

TOMMY G. THOMPSON, SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Fourth Circuit

REPLY BRIEF FOR THE PETITIONERS

TERRY E. RICHARDSON, JR.*
DANIEL S. HALTIWANGER
RICHARDSON, PATRICK, WESTBROOK & BRICKMAN
P.O. Box 1368
Barnwell, South Carolina 29812
(803) 541-7850

RICHARD J. LAZARUS
GEORGETOWN UNIVERSITY LAW CENTER
600 New Jersey Ave., N.W.
Washington, D.C. 20001
(202) 662-9129

Counsel for Petitioners

* *Counsel of Record*

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REPLY BRIEF FOR THE PETITIONERS

Respondents' brief in opposition merely parrots the opinion of the court of appeals below without making any meaningful effort to answer the arguments set forth in the petition explaining why the reasoning of that opinion is multiply flawed. Accordingly, like the court of appeals, respondents fundamentally misapprehend this Court's nondelegation doctrine precedent and then misapply it to the provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (1996), challenged in this case. So too, respondents merely echo the court of appeals' failure to enforce Congress's clear intent to confine the Secretary's

rulemaking authority to promulgate medical privacy standards to a series of specifically-listed electronic transactions of medical records. Ignoring the plain meaning of the statutory language that Congress actually enacted, they propose in its place a sweeping claim of inherent administrative agency authority to promulgate any regulations that the Secretary can deem to be "reasonably related" to statutory purposes.

Neither the nondelegation doctrine nor the plain meaning of HIPAA, however, can be so blithely cast aside. Respondents are no doubt correct that serious nondelegation problems rarely arise. But the validity of that threshold proposition does not detract from the very serious constitutional problems created when, as here, Congress plainly transgresses those boundaries. When, moreover, the Secretary compounds Congress's constitutional error by promulgating sweeping medical privacy rules that declare for the first time national standards for disclosing the intimate details of a person's health, this Court should not condition plenary review on the subsequent development of a circuit conflict. Such a profound challenge to separation of powers' principles on a sensitive and fundamentally important issue of federal law warrants review without further postponement.

1. Contrary to the respondents' claim (Br. in Opp. 8), we do not contend that Congress cannot vest rulemaking authority on subject matter that is "controversial." We repeat only what this Court has itself made recently clear, which is that "the degree of agency discretion varies according to the scope of the power congressionally conferred" and that for "setting * * * standards that affect the entire national economy," such as the Secretary's medical privacy standards," Congress "must provide substantial guidance." Whitman v. American Trucking Ass'n, 531 U.S. 457, 475 (2001).

As described in the petition, HIPAA fails to provide even the most minimal guidance, let alone the "substantial guidance" constitutionally required. Respondents try mightily to glean from the statute some relevant guidance, but at the end of the day their efforts utterly fail for one simple reason. No such statutory guidance exists within the four corners of HIPAA. Completely absent from the statute is even the most minimal guidance concerning what factors should be considered in assessing the privacy concerns implicated by particular medical records or what factors should be relevant in assessing the social policy objectives allegedly favoring disclosure of those records.

The brief in opposition, like the court of appeals opinion, argues otherwise, but only by obfuscating the essential distinction between Congress's imposing some outerbounds on the Secretary's rulemaking authority with the legislature's failure to provide the requisite intelligible principle for the exercise of that authority *within* those bounds. The nondelegation doctrine is not satisfied by the former without any regard to the latter. Indeed, were the rule otherwise, the Clean Air Act provisions recently at issue in *American Trucking Ass'n*, would have passed constitutional muster on the ground that Congress had instructed the Environmental Protection Agency to enact "national ambient air quality standards" without any additional guidance. But this Court's opinion makes clear that the Constitution does require more, which is why the Court rejected the nondelegation doctrine challenge only upon concluding that Congress had sufficiently cabined EPA's rulemaking authority by instructing that national air quality standards must be set "at the level that is 'requisite' -- that is, not lower or higher than is necessary -- to protect the public health with an adequate margin of safety." 531 U.S. at 475-76.

The degree of congressional guidance necessary for the

establishment of national medical privacy standards must be at least as great as that necessary for national ambient air quality standards. Indeed, it is hard to imagine very many social issues that touch upon the personal lives and privacy of individual Americans as does the potential disclosure of their medical records. Yet, as described in the petition (Pet. 16-19), none of the HIPAA provisions cited by the court of appeals (or the brief in opposition) bears any direct relation to the Secretary's exercise of lawmaking in setting the medical privacy standards challenged in this case. HIPAA's statement of purpose to "encourage, rather than discourage, the use of electronic data transmission" (Br. in Opp. 9) provides no "substantial guidance" on the content of the medical privacy rules, or even purports directly to address the issue at all. Nor does HIPAA's provision that rules "must 'be consistent with the objective of reducing the administrative costs of providing and paying for health care'" (Br. in Opp. 10, *quoting* 42 U.S.C. §1320d-1(b)). Both these generic legislative policy statements concern matters largely incidental to the propriety of disclosure of individual medical records. Neither remotely seeks to instruct the Secretary regarding how to address the difficult and complex privacy issues underlying the sweeping national medical privacy standards ultimately promulgated.

Respondents ultimately seek defense (Br. in Opp. 10-11) in the fact that this Court has previously rejected nondelegation challenges to federal statutes that contain only broadly-worded guidance to an agency for the exercise of its delegated lawmaking authority. As this Court made clear in *American Trucking Ass'n*, however, there is no merit to respondents' apparent assumption that the Court applies a "one size fits all" approach in nondelegation doctrine cases. "[T]he degree of agency discretion that is acceptable varies according to the scope

of the power congressionally conferred." 531 U.S. at 475. For that reason, respondents' reliance on the Court's upholding of laws containing broad delegation of lawmaking authority in other statutory contexts is entirely misplaced.

But, in all events, even those other statutes purported at least to address the substantive factors to be considered and offered some suggestion as to how the agency should strike the balance between competing factors. Without conceding that the "public convenience, interest, or necessity" standard applicable to the Federal Communications Commission (see National Broad. C. v. United States, 319 U.S. 190, 215, 225 (1943)) would have been sufficient to sustain a delegation of authority to the Secretary to promulgate national medical privacy standards, even that general standard offers far more of an intelligible principle than does HIPAA, which provides no standard applicable to privacy at all. Certainly, the substantive criteria set forth by respondents (Br. in Opp. 11) from the Occupational Safety and Health Act of 1970, instructing the agency to set a standard for toxic materials "to the extent feasible" and capable of ensuring that "no employee will suffer any impairment of health" provides several orders of magnitude more guidance than does HIPAA. The former statute addresses the substance of the rules to be promulgated, describes the extent of protection to be provided (guarding against "any impairment of health"), and emphasizes the need for "feasible" limits. HIPAA never offers any comparable guidance concerning the extent to which personal privacy should be safeguarded or how the relevant tradeoffs between competing policy concerns should be considered and determined.

The legislative record also makes clear that the absence of any substantial guidance in HIPAA is no happenstance.

As described in the petition (Pet. 11-14), Congress created this extreme result in a failed effort to force its own legislative hand on difficult policy issues that members of Congress and the President all understood required such substantial guidance. But, whatever the reasons for that effort or its failure, they cannot cure or otherwise excuse the fundamental constitutional defect thereby created when the Secretary agreed to carry through the congressional threat of providing no guidance at all.

2. Similarly lacking in merit is respondents' defense of the Secretary's decision to promulgate medical privacy standards applicable to all personal medical records regardless of their form or method of transmission. As set forth in the petition (Pet. 20-26), the relevant statutory language in HIPAA Section 264(c)(1) expressly limits the Secretary's standard setting authority "to the privacy of individually identifiable health information transmitted in connection with the transactions described in section 1173(a) of the Social Security Act." 42 U.S.C. § 1320d-2 note. Section 1173(a) of the Social Security Act in turn describes in detail nine specific transactions and limits the Secretary's rulemaking authority to the setting of standards "to enable health information to be exchanged electronically." 42 U.S.C § 1320d-2(a)(1). An unbridgeable gulf, therefore, exists between the plain meaning of the statutory language and the Secretary's decision in the final regulations to issue privacy standards applicable to personal medical records "transmitted or maintained in any . . . form or medium" 45 C.F.R. § 160.103 (2003).

Here too respondents repeat (Br. in Opp. 13) the court of appeals' error that the Secretary's action can be sustained because HIPAA defines "health information" for use throughout the statute as including "any information, whether oral or recorded in any form or medium." 42 U.S.C. § 1320d(4). The short answer, of course, is that

Section 264(c)(1)'s conferral of rulemaking authority on the Secretary does not refer simply to "health information" but instead only to "health information transmitted in connection with the transactions described in section 1173(a) of the Social Security Act."

Respondents alternatively seek to avoid HIPAA's plain meaning by offering for the first time their own construction of the statutory reference to "health information transmitted 'in connection with' the transactions described in Section 1173." Br. in Opp. 14. According to respondents (*id.*), "in connection with" means "related in some way to" the statutorily specified transactions. We believe that "in connection with" means just what it says, which is that the health information must be transmitted in connection with one of the electronic transactions referred to in the statute. Respondents plainly cannot substitute their own preferred language for that actually appearing in HIPAA. Nor can their litigating counsel in any event proffer a new interpretation before this Court for the first time and claim entitlement to judicial deference. See Investment Company Institute v. Camp, 401 U.S. 617, 628 (1971) ("Congress has delegated to the administrative official and not to appellate counsel the responsibility for elaborating and enforcing statutory commands."); Bowen v. Georgetown Univ. Hospital, 488 U.S. 204, 212 (1988).

Without a doubt, however, respondents' most sweeping claim is their embracing of the court of appeals' ruling that the Secretary possesses inherent authority to enact any regulations that the Secretary deems are "'reasonably related to the larger purposes of HIPAA.'" Br. in Opp. 14, quoting Pet. App. A14. No agency, however, possesses any such inherent rulemaking authority. It cannot be gainsaid that the Secretary's rulemaking authority is strictly confined to that expressly

conferred upon the Secretary by Congress. With regard to the medical privacy standards at issue in this case, moreover, the clear beginning and end of the Secretary's authority is that provided for by HIPAA Section 264(c)(1). No broader inherent rulemaking authority exists that permits the Secretary to ignore Section 264(c)(1)'s limitation on the Secretary's rulemaking authority to promulgate medical privacy standards.

Finally, respondents do not even try to answer the petition's showing (Pet. 22) that a comparison of the language of Section 264(c)(1) to Section 264(a) makes plain the deliberateness of the narrow rulemaking authority set forth in Section 264(c)(1). In Section 264(a), Congress did not similarly limit the Secretary's authority in describing the scope of recommendations the Secretary should make to Congress on medical privacy standards. Nor do respondents make any effort to dispute the petition's further showing (Pet. 22-23) that the legislative record reveals precisely why Congress made that policy decision to limit the rulemaking authority to the nine transactions specified in Section 1173(a): Congress was otherwise promoting the electronic transmissions of those nine transactions by establishing uniform standards and therefore was aware of the concomitant need for some interim rulemaking authority to establish medical privacy standards for them.

Respondents offer no answer to the petition in any of these respects because there is no effective response to be made. The simple truth is that Congress conferred no authority on the Secretary to promulgate sweeping medical privacy standards applicable to all personal medical records. The Secretary understood as much in virtually all aspects of the Secretary's implementation of HIPAA, but as the previous Administration was in its final days, the Secretary unilaterally decided to seize the last

remaining opportunity to impose the kinds of broad standards that the Secretary concluded were warranted, regardless of the existence of the statutory authority to do so. Under our Constitution, however, the Secretary possesses no such unilateral lawmaking authority, whether or not the Secretary can argue that it is "reasonably related" to a statute's "larger purposes."

3. Under this Court's rules, certiorari is warranted only for "compelling reasons." S. Ct R. 10. Among the compelling reasons set forth by the Court's rule is that a federal court of appeals "has decided an important question of federal law that has not been, but should be, settled by this Court." *Id.* For the reasons set forth in the petition (Pet. 26-29), none of which respondents contest, the lawfulness of the Secretary's medical privacy standards present just such an important question of federal law. As described by the Secretary herself, these rules "establish[], for the first time, a set of basic national privacy standards" and the Secretary's rules "are likely the largest single federal initiative to protect privacy." 65 Fed. Reg. 82468. At this very moment, the Secretary's standards are requiring thousands of medical providers to change dramatically their business practices and disclosure policies, thereby affecting the rights of millions of Americans on core matters of personal privacy.

The absence of any legislative authority for these standards, let alone the constitutionally-required substantial congressional guidance for the exercise of such authority, is no mere technical deficiency. With regard to medical privacy standards in particular, there is heightened reason to be wary of executive branch usurpation of lawmaking authority in the absence of legislation enacted by the democratically elected representatives. As underscored by the disclosure policies contained within the Secretary's standards, which

allow in many circumstances for disclosure of personal medical information to government agencies, including law enforcement officers (see 45 C.F.R. § 164.512, 67 Fed. Reg. 53226-32 (2002)), this is an area of law where the need to adhere to the Framers' careful design of lawmaking checks and balances is absolutely essential. This is not therefore the kind of case wherein it is proper to indulge the normal practice of postponing further review until the lower courts have the opportunity to consider further the legal issues herein presented.

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For the foregoing reasons and those set forth in the petition, it is respectfully submitted that the petition for a writ of certiorari should be granted.

TERRY E. RICHARDSON, JR.*
DANIEL S. HALTIWANGER
RICHARDSON, PATRICK, WESTBROOK & BRICKMAN
P.O. BOX 1368
BARNWELL, SOUTH CAROLINA 29812
(803) 541-7850

RICHARD J. LAZARUS
GEORGETOWN UNIVERSITY
LAW CENTER
600 NEW JERSEY AVE., N.W.
WASHINGTON, D.C. 20001
(202) 662-9129

Counsel for Petitioners

* *Counsel of Record*

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